

### **DETAILED ACTION**

This is the third Office Action following the second Request for Continued Examination based on the 10/725374 application filed December 3, 2003. Claims 26, 27, 29-32, and 35-46 as amended September 28, 2009 are currently pending and considered below.

#### ***Response to Amendment***

1. In response to applicant's arguments to the claims, the previous claim objections and the previous rejection under 35 U.S.C. 112 second paragraph.

#### ***Claim Objections***

2. Claim 41 is objected to because of the following informalities: the claim does not end in a period (--.--). Appropriate correction is required.
3. Claim 39 is objected to as it does not claim dependence upon any other claim. However, the applicant appears to have intended claim 39 to be dependent from claim 36, and the examiner has examined the claims as such.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 26, 27, 29, 30, 35, 36, 38-43, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,569,200 to Umeno et al.

Regarding claim 26, Umeno et al disclose a catheter (20) comprising: a catheter shaft having a distal end (7) and a proximal end (6), the proximal end including a bending section (31) extending distally from the proximal end toward but not to the distal end (Fig. 6), the bending section comprising one or more spiral cuts (22e) in the catheter shaft, the bending having a flexibility greater than the flexibility of the portion of the catheter shaft adjacent the bending section (Col. 7, lines 51-57); a balloon secured to the distal end (23); a fitting (30) secured to the proximal end of the catheter shaft, the fitting including a passageway in fluid communication with the catheter shaft (24, 29); and a fluid impermeable covering (22a) extending from the bending section toward but not to the distal end of the catheter shaft to seal the bending section.

Furthermore, regarding claims 27, 29, and 30, Umeno et al disclose that the fitting is a luer fitting (29, 31), that the spiral cut is formed with a selectable number of spiral sections (Figs. 3 and 4), and that the fluid impermeable covering is shaped as a sleeve or tube (22a).

Regarding claim 35, Umeno et al disclose a catheter (20) comprising: a fitting (30) including a passageway (24, 29); a catheter shaft having a distal end (7) and a proximal end (6), the proximal end being coupled to the fitting (Fig. 5) in fluid communication with the catheter shaft, the proximal end including a bending section (31) extending distally from the proximal end toward but not to the distal end (Fig. 6), the bending section comprising one or more cuts (22e) in the catheter shaft, the

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bending having a flexibility greater than the flexibility of the portion of the catheter shaft adjacent the bending section (Col. 7, lines 51-57); and a fluid impermeable covering (22a) extending from the bending section toward but not to the distal end of the catheter shaft to seal the bending section, a proximal portion of the fluid impermeable covering located within the passageway of the fitting (Fig. 5).

Regarding claims 36 and 38-40, Umeno et al further disclose that the one or more cuts are spiral cuts (22e; Figs. 3, 4, 6), that the catheter further comprises a balloon at the distal end (23), that the cuts increase in pitch toward the distal end (Fig. 4), and that the fitting is a Luer fitting (29, 31)

Regarding claim 41, Umeno et al disclose a catheter (20) comprising: a catheter shaft having a distal end (7), a proximal end (6), and a first outer cross-sectional diameter (22), the proximal end including a bending section (31) extending distally from the proximal end toward but not to the distal end (Fig. 6), the bending section comprising one or more cuts (22e) in the catheter shaft, the bending having a flexibility greater than the flexibility of the portion of the catheter shaft adjacent the bending section (Col. 7, lines 51-57); a balloon secured to the distal end (23); a fitting (30) secured to the proximal end of the catheter shaft and having a second inner cross-sectional diameter greater than the first outer cross-sectional diameter (at distal end of 30, 22 fits inside, and therefore the inner diameter of 30 is greater than the outer diameter of 22 when assembled); and a fluid impermeable covering (22a) extending from the bending section toward but not to the distal end of the catheter shaft to seal the bending section.

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Regarding claims 42, 43, 45, and 46, Umeno et al further disclose that the one or more cuts are spiral cuts (22e; Figs. 3, 4, 6), that the fitting comprises a transition member coupled to the catheter shaft (distal-most portion of fitting 30; Fig. 5), that the catheter further comprises an inflation device coupled to the fitting for expanding the balloon (31), and that the fitting is a luer fitting (29, 31).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 31, 32, 37, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeno et al.

Regarding claim 31, Umeno et al teach the device of claim 26 as described above, but fail to teach or disclose that the fluid impermeable covering is adhesively bonded to the bending section. The examiner notes, however, that Umeno et al teach affixing the cover 22a to the bending section 22e, and further teach use of a heat-shrinkable tube to attach cover 22a to bending section 22e. The examiner notes that, in light of these disclosures, it would have been obvious to one having ordinary skill in the art to use an adhesive to attach the fluid impermeable covering to the bending section as it would constitute a simple substitution of one known element (adhesive) for another (heat sealing).

Regarding claims 32, 37, and 44, Umeno et al teach the device of claims 26, 35, and 43 as described above, but fail to teach that the transition member extends over a portion of the bending section in order to prevent unintended kinking in at least a portion of the bending section. The examiner has noted that the distal-most portion of Umeno et al, having a smaller diameter as shown in Figure 5, constitutes the transition member. At the time of invention, it would have been obvious to one having ordinary skill in the art to place the bending section shown (31) at any portion of the catheter where additional flexibility was desired, including at the most extreme proximal end of the

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device, such that a portion of the bending section is at the proximal terminus of outer tube 22 and thus inserted into the transition member. Such a configuration would allow for flexibility in the placement of the fitting 30 with respect to the patient when the device is in use.

### ***Response to Arguments***

10. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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